510K Summary

Supplement 3

MAY 8 2013

Date: February 28, 2013

Submitted by: Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
2568 Bristol Circle
Oakville, Ontario
Canada L6H 5S1

Contact Person: Daniel Ramirez
Clinical Scientist
Natus Medical Inc.
Tel.: (905) 829-5300 ext 356
Fax.: (905) 829-5304
E-mail: Daniel.Ramirez-Rodriguez@natus.com

Propietary Name: Olympic Brainz Monitor (OBM)

Device Name: Olympic Brainz Monitor

Model: Olympic Brainz Monitor (OBM)

Common Name: Electroencephalograph

Classification Name: Amplitude Integrated electroencephalograph, Automatic Event Detection Software for Full-Montage Electroencephalograph, Reduced- Montage Standard Electroencephalograph

Product code: OMA, OMB, OMC

Device Class: II

Predicate Devices: Olympic Brainz Monitor (K093949)
IndenEvent (K092039)
Persyst Reveal (K011397)

The Olympic Brainz Monitor[1] is a three-channel electroencephalograph (EEG) system, as per 21 CFR §882.1400: a device used to measure and record the electrical activity of the patient's brain by placing two or more electrodes on the head. The device does not introduce, transfer or deliver any type of energy to the patient. As any other electroencephalograph the device passively record the

[1] Internal (Engineering) name of the Olympic Brainz Monitor is CFM7000.

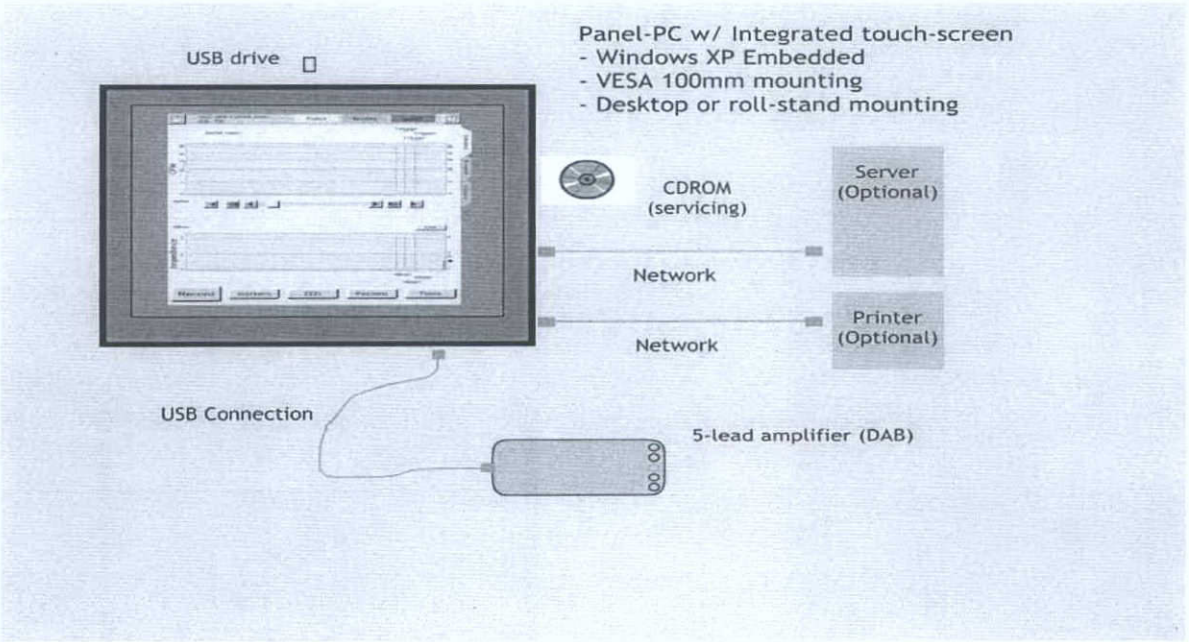
electroencephalographic activity from the patient trough the hydrogel electrodes and then process the signal for display, analysis and archiving.

The Olympic Brainz Monitor system consists of the following:

- Data Acquisition Box (DAB)
- Touchscreen Monitor
- Roll Stand or optional Desktop Stand
- Neonatal Sensor set (K033010)
- Software

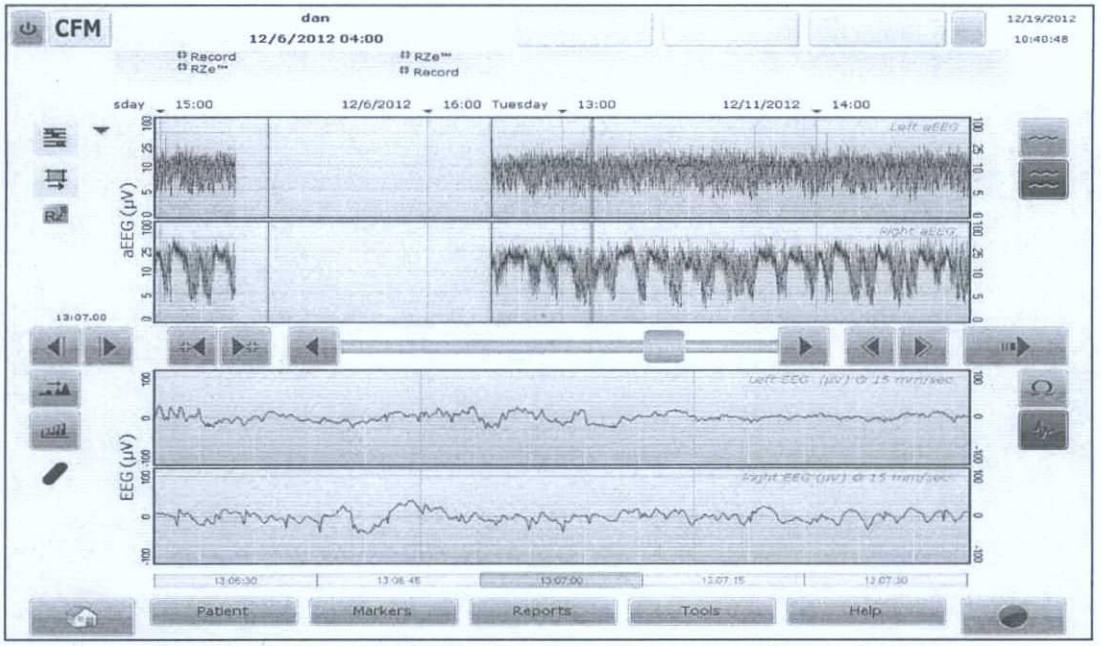
These components have equivalent configuration and functions to those described in K093949 for the OBM Monitor. The Neonatal Sensor set (cleared on K033010) is an accessory to the device that is the only part that enters into contact with the patient. The sensor guarantees acquisition of the electroencephalographic signal and passively transfers it to the main unit. This is a set of five hydrogel skin electrodes that are attached to the patient's head at one extreme and to the Data Acquisition Box at the other extreme using standard touch-proof connectors.

An overview of hardware connectivity and system connectivity is illustrated below.



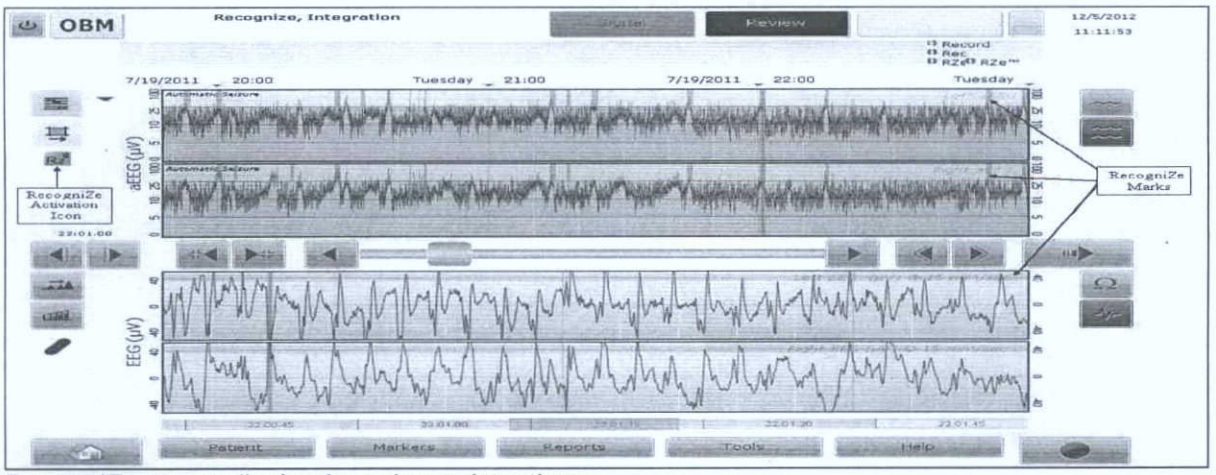
Olympic Brainz Monitor Connectivity

The device allows practitioners to acquired, store, review and archive EEG activity from 4 centro-parietal locations corresponding to C3, C4, P3 and P4 of the international 10-20 System. The device displays the recorded activity in form of the raw EEG and as amplitude integrated EEG (aEEG).



Real-time (EEG Waveform, aEEG) for the bilateral channels (C3-P3, C4-P4)

In addition the device now includes a seizure detection algorithm (i.e RecogniZe) to allow automated analysis of the recorded EEG. The RecogniZe Seizure Detection Algorithm identifies sections of the EEG trace where seizure activity is detected. The algorithm comprises filtering of the EEG signal, fragmentation of EEG signal into waves, wave-feature extraction, and elementary, preliminary and final detection. The main idea behind the algorithm is to detect heightened regularity in EEG wave sequences using wave intervals, amplitudes and shapes, as increased regularity is the major distinguishing feature of seizure discharges.



RecogniZe output display for seizure detections.

Indications for Use

The Olympic Brainz Monitor (OBM) is a three channel electroencephalograph (EEG) acquisition system intended to be used in a hospital environment to record, collect, display and facilitate manual marking of aEEG recordings.

- The signals acquired from P3-P4, C3-P3 and C4-P4 channels are intended for use only with neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a postconceptual age of 24 to 46 weeks) to display aEEG for monitoring the state of the brain.
- The signals acquired from P3-P4 channel is intended to assist in the assessment of Hypoxic-Ischemic Encephalopathy severity and long-term outcome, in full term neonates (postconceptual age of 37-46 weeks) who have suffered a hypoxic-ischemic event.
- The RecogniZe seizure detection algorithm is intended to mark sections of EEG/aEEG that may correspond to electrographic seizures in only the centro-parietal regions of full term neonates (defined as from birth to 28 days post-delivery, and corresponding to a post-conceptual age of 37 to 46 weeks). EEG recordings should be obtained from centro-parietal electrodes (located at P3, P4, C3 and C4 according to 10/20 system). The output of the Recognize algorithm is intended to assist in post hoc assessment of EEG/aEEG traces by qualified clinical practitioners, who will exercise professional judgment in using the information.

The Olympic Brainz Monitor does not provide any diagnostic conclusion about the patient's condition.

Predicate Comparison

Device Feature	Subject Device: OBM Brain Monitor	Predicate Device OBM Brain Monitor (K093949)
Intended Use...		
Purpose and function:	EEG monitoring	EEG monitoring
Patient population:	Neonatal	Neonatal
Environment of use:	Clinical environments (NICU, research)	Clinical environments (NICU, research)
Hardware Features...		
Physical platform:	Mobile roll-pole	Mobile roll-pole
EEG system platform:	Pentium M, panel PC	Pentium M, panel PC
Display type:	15" color LCD	15" color LCD
Device control method:	Touch-screen GUI	Touch-screen GUI
Mains power transformer:	Internal to Monitor (monitor houses a medical grade power supply)	Internal to Monitor (monitor houses a medical grade power supply)
Skin Electrodes (K033010)		
Electrode configuration:	4 signal electrodes + reference	4 signal electrodes + reference
Shelf Life	18 months	18 months
Sterile	NO	NO
Leadwire configuration:	Standard touch-proof connections on OBM DAB	Standard touch-proof connections on OBM DAB
DAB (Amplifier) Performance...		
Maximum number of channels:	3	3
A-to-D converter:	4-channel multiplexed successive-approximation type	4-channel multiplexed successive-approximation type
Sampling rate:	2000 Hz	2000 Hz
Sampling resolution:	16 bits at 2000 Hz	16 bits at 2000 Hz
Input impedance:	50 MΩ@ 10Hz	50 MΩ@ 10Hz

Device Feature	Subject Device: OBM Brain Monitor	Predicate Device OBM Brain Monitor (K093949)
Noise in bandwidth:	< 1 μV_{P-P} 1~15Hz	< 1 μV_{P-P} 1~15Hz
Common-mode rejection:	> 100 dB @ 60Hz	> 100 dB @ 60Hz
Sensitivity for max DAB output:	± 5 mV_{PK}	± 5 mV_{PK}
Calibration:	One-time at factory only	One-time at factory only
Bandwidth:	0.5Hz ~ 450Hz	0.5Hz ~ 450Hz
Impedance monitoring:	Continuous on each electrode	Continuous on each electrode
Impedance check signal:	6 nA_{rms} at 353, 375, 400, 429Hz	6 nA_{rms} at 353, 375, 400, 429Hz
Functional test equipment:	none	none
Signal Quality...		
Impedance alarm limits	15 kΩ Warning messages and troubleshooting suggestions. Color coded indications of impedance levels.	15 kΩ Warning messages and troubleshooting suggestions. Color coded indications of impedance levels.
Signal quality indication	Continuous impedance check. Continuous display of impedance values/trace.	Continuous impedance check. Continuous display of impedance values/trace.
Notch filter	Yes 50/60 Hz	Yes 50/60 Hz
Displayed Parameters...		
Main parameters	EEG, aEEG waveform	EEG, aEEG waveform
Secondary parameters	None	None

Device Feature	Subject Device: OBM Brain Monitor	Predicate Device OBM Brain Monitor (K093949)
Signal reliability parameters	Continuous Impedance values/trace	Continuous Impedance values/trace
Monitor Features...		
Patient identification data	Shows patient name, date of birth, time of birth and ID	Shows patient name, date of birth, time of birth and ID
Event marking	Yes. User can mark areas of interest.	Yes. User can mark areas of interest.
Recorded file reviewing.	Yes, on screen or printed record.	Yes, on screen or printed record.
External Interfaces...		
Output to printer:	via Ethernet port	via Ethernet port
External data storage:	via USB port	via USB port
Software upgrades:	via USB port	via USB port
Standards Compliance...		
General & electrical safety:	IEC 60601-1	IEC 60601-1
US national deviations:	UL 60601-1	UL 60601-1
EEG particular requirements:	IEC 60601-2-26	IEC 60601-2-26
Electromagnetic compatibility:	IEC 60601-1-2	IEC 60601-1-2

Predicate Comparison for aEEG feature

	Subject Device: OBM Brain Monitor	Predicate Device OBM Brain Monitor (K093949)
a) Device Class	Class II	Class II
b) Class Name	Electroencephalograph	Electroencephalograph
c) User input	Touch-screen	Touch-screen

	Subject Device: OBM Brain Monitor	**Predicate Device OBM Brain Monitor (K093949)**
d) Have aEEG tracing	Yes	Yes
e) Have raw EEG tracing	Yes	Yes
f) Simultaneous and synchronized aEEG an raw EEG display	Yes	Yes
g) Shows Impedance measurements	Continuous trace	Continuous trace
h) aEEG signal processing algorithm	Filtered by aEEG filter, rectified and semi logarithmically compressed	Filtered by aEEG filter, rectified and semi logarithmically compressed
i) aEEG filter specification	Up to 2 Hz: Rising by 60 dB/decade 2 Hz - 12 Hz: Rising by 12 dB/decade 12 Hz - 16 Hz: 1 dB above 10 Hz level 16 Hz - 30 Hz: cut off slope 120 dB/decade 50 Hz and above 60 dB down on 10 Hz response	Up to 2 Hz: Rising by 60 dB/decade 2 Hz - 12 Hz: Rising by 12 dB/decade 12 Hz - 16 Hz: 1 dB above 10 Hz level 16 Hz - 30 Hz: cut off slope 120 dB/decade 50 Hz and above 60 dB down on 10 Hz response
j) aEEG display scale	Semi logarithmic scale from 0 to 100 micro Volts.	Semi logarithmic scale from 0 to 100 micro Volts.
k) Number of electrodes	4 active electrode + 1 reference	4 active electrode + 1 reference
l) Location of electrodes	Centro-parietal corresponding to C3, C4, P3 and P4 locations of the 10/20 System	Centro-parietal corresponding to C3, C4, P3 and P4 locations of the 10/20 System

	Subject Device: OBM Brain Monitor	**Predicate Device OBM Brain Monitor (K093949)**
m) CFM Display Controls	User can move through the aEEG trace data by touching the scroll bar or navigation buttons on the screen. User can scroll by page, or by Markers.	User can move through the aEEG trace data by touching the scroll bar or navigation buttons on the screen. User can scroll by page, or by Markers.
n) EEG display and positioning Controls	1. Each EEG screen contains up to 15 seconds of EEG data. The default represents about 30 mm/sec or about 7 seconds of data. 2. EEG amplitude display ranges from 50 micro Volts (p-p) to 800 micro Volts (p-p). 3. User can move through the EEG forwards and backwards.	1. Each EEG screen contains up to 15 seconds of EEG data. The default represents about 30 mm/sec or about 7 seconds of data. 2. EEG amplitude display ranges from 50 micro Volts (p-p) to 800 micro Volts (p-p). 3. User can move through the EEG forwards and backwards.
o) Additional controls	Record – user can press the Record button to start or stop recording.	Record – user can press the Record button to start or stop recording.

No changes have been implemented to the OBM monitor since its clearance (K093949). The intended use, components, parts, materials and technological characteristics of the subject device, are the same as those described and cleared on K093949.The subject device is in all regards the same as the cleared OBM K093949.

The skin electrodes (also referred to as "sensors") provided for use with the OBM Brain Monitor is the Neonatal Sensor Set. This is a set of five hydrogel skin electrodes with standard touch-proof connectors that attach to the Data Acquisition Box. This sensor set was cleared under K033010.

The sole difference between the subject device and that cleared on K093949 is the addition of the RecogniZe, seizure detection module. A new intended use claim has been added to the subject OBM device IFU, to address the addition of this new component.

Predicate Comparison for Seizure Detection.

	Subject Device: **OBM Monitor (RecogniZe)** **K123079**	**Predicate Device**	
		IndentEvent K092039	**Persyst Reveal K011397**
Product Code	OMA, OMC	OMB, OLT	GWS
Identifies seizures	YES	YES	YES
Intended Use	to mark sections of EEG that may correspond to electrographic seizures	to mark sections of EEG that may correspond to electrographic seizures	to mark sections of EEG that may correspond to electrographic seizures
Population	Neonatal	Adult	Adult
Number of Channels	4 (C3,C4,P3 and P4)	16 (standard 10/20 system)	Unknown
Type of recording supported	Raw EEG (scalp only)	Raw EEG (scalp only)	Raw EEG (scalp only)
Type of analysis	Post-hoc	Post-hoc	Post-hoc
User Adjustable	YES	YES	YES
Output	Visible marks on EEG/aEEG signal display.	Visible marks on EEG signal display.	Visible marks on EEG signal display.
Positive Percent Agreement (%)	61%	79.5%	74%
False Detection Rate (FP/h)	0.6	0.08	0.3

RecogniZe is substantially equivalent to the cleared seizure detection algorithms IndentEvent (K092039) and Persyst Reveal (K011397).The subject devices as the predicates use raw EEG signal as the basis to carry their function i.e. analysis of the acquired EEG signal for seizure detection. As in the predicate devices, users of RecogniZe are provided with the possibility to adjust detection parameters that control the seizure detection capabilities. The output of the Recognize seizure detector, as that of the predicates, is marked EEG regions where the probable seizure activity is present. Similar to the predicates, the intended user of the subject device is a qualified medical practitioner who will review the marked EEG traces and use the information according to their professional judgment. As the predicates, RecogniZe is intended as a tool to aid in the assessment of long EEG recordings to help reduced the amount of time devoted to review. RecogniZe, as the predicates, does not provide any diagnostic conclusion.

Technological differences between RecogniZe and the predicates include the number and location of channels. Predicates use at least 16 channels while RecogniZe uses 3 channels located in C3, C4, P3 and P4 of the 10/20 System for Electrode Placement. We have shown in the clinical study that the majority of seizures in the neonate occur or are visible at centro-parietal electrodes. Risks associated with non-visible/detectable seizures have been mitigated trough detailed communication to the user and instructions for use of the device.

Predicate devices are intended for adult patients while the subject device is intended for neonates. Intrinsic differences on the EEG for both groups prevent us from comparing performance of predicates in neonates. However, substantially equivalence of RecogniZe is established through clinical testing proving that RecogniZe as the predicates is equivalent to performance of medical experts. Predicates have all been cleared based on their comparison to similar devices and to performance of expert encephalographers. In all cases performance of the predicates is comparable to that of the medical experts which has served as the basis for demonstration of safety, effectiveness and substantial equivalence. In this sense, RecogniZe performance is comparable to the predicates, i.e. RecogniZe performance is similar to that of the expert encephalographers confronted with a similar task. Therefore we claim Recognize is substantially equivalent to predicate devices.

Brief Summary of Non-Clinical and Clinical Performance Tests

All functionalities and performance of the Olympic Brainz Monitor have been verify/validated through Bench and clinical performance tests according to the intended use- and user- of the device.

Non-Clinical: The OBM device is compliant with all currently accepted safety standards for medical devices of its class which was demonstrated through testing, verification and validation of all components.

Clinical: Natus conducted an extensive clinical test to: 1) Evaluate the positive percent agreement (i.e., detection sensitivity) and false detection rate of RecogniZe, seizure detection algorithm, and to 2) Demonstrate equivalence of the seizure detection performance, in terms of positive percent agreement and false detection rates, of RecogniZe as compared to the gold standard, defined as seizures detected by a panel of 3 EEG board certified medical professionals.

RecogniZe Clinical Validation

Testing Dataset

All EEGs used for validation were collected from neonatal patients seen for routine clinical evaluation at the Neonatal Intensive Care Unit of St. Louis Children's Hospital, USA. An independent physician not taking part on the subsequent review/scoring of the data conducted database query and study inclusion from a patient database of consecutive recordings.

All studies consisted on EEGs recorded using the Stellate Harmonie for multichannel EEG recordings obtained from scalp locations according to the International 10-20 system, and Olympic Brains Monitor for limited channel (3 channels) montage. All recordings meeting inclusion criteria were included independently of EEG patterns and technical quality.

Dataset Description:

Number of Events: 421

Total Number of Patients: 82

Number of Hours: 621

AGE (Mean ± SD)	38.3 (± 1.9)
GENDER (Female/Male)	44/38

All subjects involved in this study were neonates (defined as from birth to 28 days post-delivery, and corresponding to a post-conceptual age of 37 to 46 weeks). The demographic characteristics of the population included for this study are shown below:

To avoid over-weighting recordings containing many events, a maximum of 13 events per limited-channel recording were permitted.

Analysis Method

EEG studies were de-identified, randomized and provided to board certified neurophysiologists that independently, blindly and manually marked seizures (no seizure detection algorithm was allowed) in the same manner they would normally do in clinical practice. Experts initially reviewed the full cohort of standard montage recordings (157) marking seizure onset and noting the topography of seizures. To annotate topography experts were asked to classify seizures as occurring in one of the following zones:

1. Frontal (Left/Right)
2. Centro-Parietal (Left/Right)
3. Central Midline
4. Temporal (Left/Right)
5. Occipital (Left/Right)

After a 4 weeks wash-out period implemented to avoid any possible recognition of individual recordings, reviewers were provided with the limited-channel (C3-P3, C4-P4 and P3-P4) recordings for marking. Once EEGs were marked by the expert raters same limited channel studies were submitted for analysis using RecogniZe.

Detection Parameters

To conduct the analysis, the marked studies were played back and fed into the RecogniZe software, with detection settings at default values (detection threshold was 5μV). Measurements of event-based Positive Percent Agreement (PPA) and False Detection Rate (FDR) of the proposed detection system were assessed.

The event-based 'any-overlap' method[2] was used. An Event of Interest (EOI) detected by the algorithm was considered to match an EOI marked by the expert rater if there was any intersection between their two time periods. The any-overlap positive percent agreement was calculated by dividing the number of matched events by the total number of events.

All studies were annotated by the event detection algorithm. Notes were stored in time order in an annotation file for each study and were used for comparison against the annotated EEG files generated by the expert readers. PPA and FDR were calculated on the same dataset of recordings which combined seizure and non-seizure recordings.

2 Wilson SB, Scheuer ML, Plummer C, Young B, Pacia S. Seizure detection: correlation of human experts. Clin Neurophysiol. 2003 Nov;114(11):2156-64.

Results

Electrographic Seizure Topography.

The table below describes the topographical distribution of seizures detected with standard montage on conventional EEG recordings. According to majority rule, there were a total of 635 seizures in all recordings

Zone	% visible seizures
Frontal (Left+Right)	17.1% (109)
Central Midline	19.6% (125)
Centro-Parietal (Left+Right)	54% (340)
Temporal (Left+Right)	6.7% (43)
Occipital (Left+Right)	2.8% (18)
Total	635

We have collapsed seizures from homologous zones (i.e temporal left + temporal right, and so on). The most common location of seizures was the centro-parietal zones where 73% (465/635) of seizures occurred followed the frontal zones (17%, 109/635). Seizures visible in the occipital zones were the less frequent.

Inter Rater Performance

1. *Conventional EEGs (cEEG)*

Inter-rater Positive Percent Agreement and False Detection / hour with cEGG

	EVENTS					
	Rater 1		Rater 2		Rater 3	
	PPA%	FD/h	PPA%	FD/h	PPA%	FD/h
Rater 1			81	0.2	81	0.2
Rater 2	78	0.2			57	0.2
Rater 3	78	0.2	80	0.2		

The inter-rater agreement reported in our study varies between 78 % and 81% for seizure detection while FDR (false detection per hour (FD/h) was very close for all three raters (0.2 FD/h).

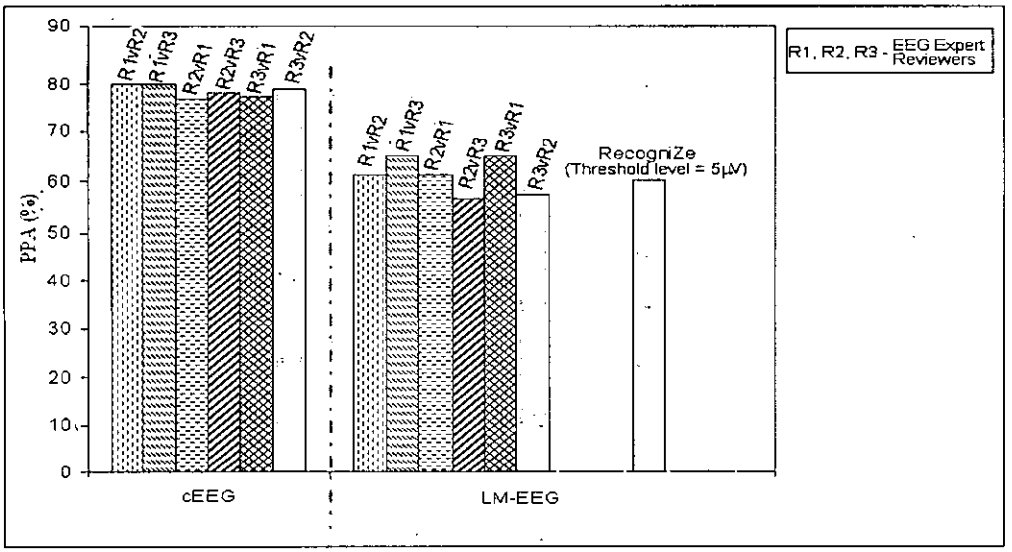
2. Limited Channel EEG

Inter-rater PPA for scorer to scorer ranged between 58 and 66%, while FDR (false detection per hour (FD/h) was very close for all three raters (0.3 FD/h).

Inter-rater Positive Percent Agreement and False Detection / hour with OBM

	EVENTS					
	Rater 1		Rater 2		Rater 3	
	PPA%	FD/h	PPA%	FD/h	PPA%	FD/h
Rater 1			62	0.3	66	0.3
Rater 2	62	0.3			57	0.3
Rater 3	66	0.2	58	0.2		

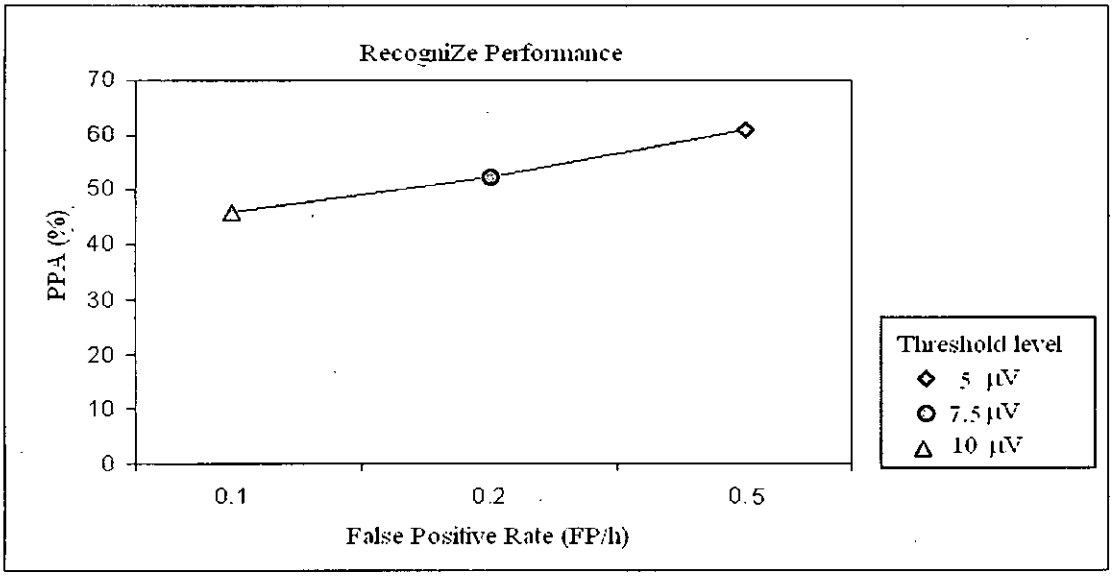
The inter-rater agreement reported in our study varies between 58 % and 66% for seizure detection. Evaluating inter-rater agreement for seizure detection Walczak et al (1992) reported that seizure onset was correctly determined by 3 independent EEGers in 47% to 65% of extratemporal seizures like is the case for the study reported here where information available to EEGers was recorded at extratemporal (centro-parietal) sites.



Seizure recognition by expert reviewers is better when conventional EEG (cEEG) is used as compare to same task but with a Limited Channel Montage (LM-EEG). Expert reviewers detected a total of 635 seizures in cEEG versus 424 seizures in the LM-EEG. RecogniZe detected 258 seizures in the LM-EEG. With the limited number of channels, there are less visual cues available to perform the patter-recognition task necessary for seizure identification. This however, does not prevent seizure recognition, but somehow increases the difficulty of the task at hand.

Algorithm Performance

The picture below presents RecogniZe performance using the full range of detection thresholds: 5μV, 7.5 μV and 10 μV.



The results revealed that as detection threshold increases the False Positive Rate improves (less False Positives per hour) at the expense of deterioration in the algorithm Positive Percent Agreement (PPA). With detection threshold set at 10 μV PPA drops to 47% and FDR decrease to 0.1 FP/h. With the default settings (detection threshold at 5 μV) Recognized achieved 61% positive percent agreement and a false detection rate of 0.5/hr, comparable to the range of inter-rater false detection rate of 0.3/hr and raters

Threshold level (μV)	PPA (95% CI)*	FDR (FP/h) (95% CI)*
5	61% (52 – 68)	0.5 (0.4 – 0.7)
7.5	53% (39 – 55)	0.2 (0.1 – 0.3)
10	47% (33 – 49)	0.1 (0.07 – 0.1)

*Bootstrap 95% CI

When confronted with 3 channels raw EEGs the average rater PPA was 62%. That is, any given expert EEGer positively agreed 62% on average with any of its peers for seizure identification in a limited channel montage. With a 61% PPA and an FDR of 0.5 FD/hr RecogniZe is substantially equivalent to the performance of medical experts confronted with similar task and amount of data

Conclusion:

Based on the results of the Clinical and non-clinical testing we conclude that the Olympic Brainz Monitor is safe, effective and substantially equivalent to predicates in intended use, and all other technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 08,2013

Natus Medical Incorporated
DBA Excel-Tech Ltd. (XLTEK)
Daniel Ramirez
2568 Bristol Circle
Oakville, Ontario L6H 5S1
Canada

Re: K123079
Trade/Device Name: Olympic Brainz Monitor
Regulation Number: 21 CFR 882.1400
Regulation Name: Amplitude-integrated electroencephalograph
Regulatory Class: Class II
Product Code: OMA, OMB, OMC
Dated: April 9, 2013
Received: April 12, 2013

Dear Mr. Ramirez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to: http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address: http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K123079

Device Name: XLTEK Olympic Brainz Monitor

Indications For Use:

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- The signals acquired from P3-P4, C3-P3 and C4-P4 channels are intended for use only with neonatal patients (defined as from birth to 28 days post-delivery, and corresponding to a postconceptual age of 24 to 46 weeks) to display aEEG for monitoring the state of the brain.
- The signals acquired from P3-P4 channel is intended to assist in the assessment of Hypoxic-Ischemic Encephalopathy severity and long-term outcome, in full term neonates (postconceptual age of 37-46 weeks) who have suffered a hypoxic-ischemic event.
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The Olympic Brainz Monitor does not provide any diagnostic conclusion about the patient's condition.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.05.09 14:53:25 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

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